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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,433	04/15/2005	Takeshi Ito	KUZ-0024	8651

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,433	ITO ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6,7,13,14,16,17 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6,7,13,14,16,17 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 8/12/09

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3, 6, 7, 13, 14, 16, 17, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Hori et al (USPN 5,814,032 hereafter '032). The claims are drawn to a transdermal patch formulation comprising a polyisobutylene mixture, a mineral oil and fentanyl.

The '032 patent discloses a pressure sensitive adhesive formulation comprising a mixture of high and low molecular weight (polyisobutylene in a ratio of 1:3 (high: low) (Table 1). The polyisobutylene is present in a concentration from 50-80% (col. 4, lin. 1-5). The formulation comprises fentanyl (col. 3, lin. 50-5) present in a concentration of 0.01-20 parts by weight of 10 parts (0.01-20%) (col. 3, lin. 55-65). The formulation further includes liquid paraffin and

isopropyl myristate (col. 5, lin. 35-60). The compounds are present in an amount approximately 0.5-20 parts by weight based on 100 parts (0.5-20%) (col. 6, lin. 8-16). The pressure sensitive adhesive layer measures 25 square cm and is 200 microns thick (col. 8, lin. 10-20). The concentrations of the reference overlap those of the instant invention, and would obviate the instant claims. The specific concentrations would be arrived art through routine experimentation by those of ordinary skill in the art. Also the reference is silent to the specific molecular weights of the polyisobutylene however high and low molecular weight polymers are well known and similarly weighted polymers are used in combination (col. 4, lin. 18-22). These limitations would be obvious variants and modification well within the level of skill in the art.

Regarding the claims reciting specific percentages and ratios of the polyisobutylene, mineral oil and fentanyl, it is the position of the Examiner that these limitations represent an optimization of ranges, something that is well within the level of skill in the art. Specifically the '032 patent provides a transdermal formulation comprising fentanyl, polyisobutylene where the high and low molecular weight polyisobutylene in a ratio similar to that of the instant claims, (1:3). The transdermals formulations are of the same size, shape, carry the same active compound and provide the same solubilizing agent m, liquid paraffin in comparable concentrations. Increasing or decreasing the individual components in order to affect the result of the transdermal, adjusting the active compound to make the form more potent; increasing or decreasing the carry polymer to slow or increase the delivery rate; increasing or decreasing the solubilizer in order to modulate skin irritation and response, are all result effective parameters that are well within the level of skill to be modified. The general conditions of the claims have been met by the '032 patent. Applicant is reminded that where the general conditions of a claim

are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Regarding the negative limitation recited in the claims regarding the presence of a hydrophilic polymer it is the position of the Examiner that this limitation odes not distinguish over the prior art. Applicant is reminded that it is obvious to omit a component if the function of the components is not required or desired. As such if the function of water absorption is not required by the transdermal device of the instant claims, than the omission of a hydrophilic polymer would have been an obvious modification. See Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

With these things in mind it would have been obvious to follow the teachings and suggestions in the rat to modify and perfect the concentrations of the components in order to provide a stable long term transdermal device useful in topical drug delivery. One of ordinary skill in the art would have been motivated to modify the concentrations of the components through routine experimentation since they would provide the optimal results for drug delivery. These modifications would have been obvious and resulted in a stable and safe topical formulation.

Response to Arguments

Applicant's arguments filed 8/12/09 have been fully considered but they are not persuasive. Applicant argues that:

The Hori transdermal devices do not obviate the instant claims since they require a hydrophilic water absorbing component and the instant claims clearly do not require such a component.

As discussed above it remains the position of the Examiner that the claims remain obviated by the '032 patent since it would have been obvious to omit the hydrophilic component if the desired function was not required. Applicant argues that Table 1 clearly shows that hydrophilic polymers are not present yet cohesion and skin irritation are maintained at acceptable levels while the examples of the '032 patent show the opposite. However the Examples of the '032 patent should be not be used to limit the scope of the invention. Column 6, lin. 10-15, clearly states that the transdermal devices further include up to 20 parts of an accelerator which an be liquid paraffin, while the Examples are silent to these components. As such the Examples of the instant claims are not directly compared to those of the '032 patent. The Examples of the '032 that have no hydrophilic components exhibit good adhesion, no skin irritation and only partial peeling (Comparative 1-3). These would be comparable to those of the instant claims and they perform nearly identically to those patches show in Table 1. For these reasons the claims remain obviated, since the prior art discloses similar transdermal patches comprising polyisobutylene with a ratio of high to low components within the limits of the instant claims, active agents, and carriers, all within in the ranges of the instant claims. The '032 patent further shows that the hydrophilic components are only required if water absorption is a required function, yet if water absorption is not required, a cohesion, suitable transdermal device can still be constructed and function.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618